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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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JAMES F. HALEY, JR.
FISH & NEAVE,
875 THIRD AVE.
NEW YORK, NY 10022

EXAMINER	
CRANE, L	
ART UNIT	PAPER NUMBER
183	6

DATE MAILED:

06/20/90

This is a communication from the examiner in charge of your application.

COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|--|---|
| <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449 | 4. <input type="checkbox"/> Notice of informal Patent Application, Form PTO-152 |
| <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474 | 6. <input checked="" type="checkbox"/> Memo from Comm. Manbeck |

Part II SUMMARY OF ACTION

☒ Claims 101-103, 110-112, 138, 139, & 146-151 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

☒ Claims 1-100, 104-109, 113-137, & 140-145 have been cancelled.

☐ Claims _____ are allowed.

☒ Claims 101-103, 110-112, 138, 139, 146-151 are rejected.

☐ Claims _____ are objected to.

☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings which are acceptable for examination purposes until such time as allowable subject matter is indicated.

☒ Allowable subject matter having been indicated, formal drawings are required in response to this Office action.

☐ The corrected or substitute drawings have been received on _____. These drawings are ☐ acceptable;
☐ not acceptable (see explanation).

☒ The ☐ proposed drawing correction and/or the ☐ proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved. ☐ disapproved (see explanation). However, the Patent and Trademark Office no longer makes drawing changes. It is now applicant's responsibility to ensure that the drawings are corrected. Corrections MUST be effected in accordance with the instructions set forth on the attached letter "INFORMATION ON HOW TO EFFECT DRAWING CHANGES", PTO-1474.

12. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received

☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

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The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group 180, Art Unit 183.

5 Applicant's submission of a PTO-1449 is noted. The references
noted thereon by the office were supplied by applicant for a related
case, SN 130,002. Although applicant has noted in accompanying
comments citation of certain Japanese patent applications in both
10 cases, in neither case have these documents been supplied. In
addition, applicant will note that documents not initialed have been
crossed off in pencil. Should applicant wish to supply any references
for the instant application which were not supplied for the
companion application cited supra, any additional supplied references
will be reviewed at the time of submission and noted accordingly on
15 the appropriate PTO reporting form.

20 Claims **101-103, 110-112, 138-139 and 146-151** are
rejected under the judicially created doctrine of obviousness-type
double patenting as being unpatentable over the prior invention as set
forth in claims **1-21** of U.S. Patent No. 4,711,955. Although the
conflicting claims are not identical, they are not patentably distinct
from each other because the instant claims are directed to much of
the same subject matter of the already patented claims.

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The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of monopoly by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

"The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention."

The specification is objected to under 35 U.S.C. 112, first paragraph, as failing to teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

Applicant has claim language directed to the attachment of labels to the 8-position of purines. However, there are no embodiments in the instant specification which describe how this attachment is executed in specific detail.

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Applicant has claim language directed to the attachment of labels to the 7-position of a "deazapurine." However, there are no embodiments in the instant specification which describe how this attachment is executed in specific detail. And moreover, as there are several different "deazapurine" structures possible, applicant's very indefinite claim language makes it impossible for one of ordinary skill to understand, let alone make and/or use, what is being claimed.

Claims **101-103, 110-112, 138-139 and 146-151** are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the objection to the specification.

The disclosure is objected to because of the following informalities: Applicant is requested to carefully review both the specification and the claims (paper no. 3 particularly) for spelling errors. In addition, the pages of paper no. 3, amendment B, include figures which have been taped to the page, e.g. claims **101 and 110**. Applicant is requested to submit replacement pages which conform to the MPEP as regards non-removability or erasability of printed matter or figures from the instant disclosure.

Appropriate correction is required.

Claims **101-103, 110-112, 138, 139, and 146-151** are rejected under 35 U.S.C. 112, first and second paragraphs, as the

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5 claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10 In claims **101 and 110**, the terms "purine", "deazapurine", and "pyrimidine" are unduly broad and indefinite in view of the vast arrays of structures these terms encompass in comparison with the very meager number of disclosed specific embodiments of the instant specification. Applicant is requested to limit the scope of the instant claims to the specific embodiments.

15 In claims **101 & 110** applicant limits the attachment of the moiety(ies) "A", "A'", "A" " to the "7-position" of deazapurines. Applicant is requested to note that the Ring Index and any book dealing with purine nomenclature will teach that the numbering of purines is an oddity due to the pioneering work of E. Fischer and that subsequent numbering schemes for "purine analogues", including applicant's "deazapurines," differs due to the recognition that bridgehead ring atoms are typically not chemically reactive. Hence
20 applicant's use of "7-position" in apparent reliance on the purine ring numbering scheme is incorrect. If applicant intends that "deazapurine" means --pyrrolo[2,3-d]pyrimidine--, then it appears, based on my understanding of the numbering scheme for this ring system through acquaintance with compounds like *toyocamycin*(see

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Merck Index, 10th Ed., entry 9387 at p. 1368), that applicant is actually referring to the 5-position. Appropriate clarification of what structure(s) applicant is really referring to is requested.

5 Similar criticism applies to applicant's claims directed to attachment of sugar moieties to "N-9" of a deazapurine. In the case of pyrrolo[2,3-d]pyrimidines the corresponding location is --position 7--.

10 In claims **101 & 110** the term "A represents a component of a detectable complex" is both indefinite and of excessive scope. Applicant fails to further define the upper limit on the size of "A" and also fails to further define in said claim what is intended by the term "detectable complex" in a manner commensurate with the implicit limitations of the instant disclosure.

15 In claims **101 & 110** the term "attached to the 8-position of the purine" implies enabling embodiments in the instant disclosure which are not present thus rendering the term both indefinite and unenabled, i.e. one of ordinary skill cannot make and/or use without an adequate written description.

20 In claims **101 & 110** the term "at least one" is indefinite and excessively broad due to its lack of accompanying claim language providing an upper bound.

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5 In claim **101 & 110** the last three lines of said claim as amended in amendment B imply a multi-layered immunological sandwich(es) which is/are not described in enough detail for one of ordinary skill to know the metes and bounds of what is being claimed.

In claims **102 & 111** the term "a moiety which can be detected" is functional language so broad and indefinite as to be useless in determinations of the metes and bounds of what is being claimed.

10 In claims **103 & 112** the terms "fluorescent dye", "electron dense protein", "enzyme capable of producing a detectable reaction product" amount to functional language so broad and indefinite as to be useless in determinations of the metes and bounds of what is being claimed.

15 In claim **138 and 139** the subject matter claimed in expanded further to include both 2',3'- and 3',5'-cyclic monophosphates, neither of which is represented by even a single specific embodiment.

In claim **146-148** the terms "A is a ligand" and dependent references thereto are both indefinite and unenabled in view one of ordinary skill's inability to determine which "ligand[s]" applicant intends to claim?

20 In claim **149** the terms "detectable by means inherent in the polypeptide or by means of detectable moieties which are attached thereto is both indefinite and unenabled in view one of ordinary skill's

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inability to determine the metes and bounds of the subject matter applicant intends to claim?

5 In claim **150** the term "a detectable moiety" is both indefinite and unenabled in view one of ordinary skill's inability to determine the metes and bounds of the subject matter applicant intends to claim?

10 In claim **151** the terms "enzyme", "substrate", and "detectable product" are both indefinite and unenabled in view one of ordinary skill's inability to determine the metes and bounds of the subject matter applicant intends to claim?

Appropriate correction is requested.

15 Claim **101** is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim **101** the term "N¹ position" (see p. 2, line 4 of amendment B) is incorrect, i.e. the sugar moiety has no nitrogen atoms. It appears that applicant intended -- N¹ position--.

Appropriate correction is requested.

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Applicant is requested to note that claims **101 and 110** appear to be substantial duplicates. Applicant is requested to cancel one of said claims and the claims dependent thereon.

5 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and
10 invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

15 Applicant's attention is directed to the enclosed "memo" from Commissioner of Patents Manbeck concerning communications between the PTO and applicant's representatives. As the signatory on the last communication in the instant case, Mr. James Haley, is not listed on the declaration as an attorney of record, then future *oral (telephonic)* communications will have to be with one of the aforementioned
20 attorney's of record, in writing only, or the instant declaration will need to be replaced with a declaration including Mr. Haley as an attorney of record.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is 703-557-3583.

5 Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is 703-557-0664..

LECRANE:lec

5/14/90



JOHN W. ROLLINS
PRIMARY EXAMINER
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